

Interview Summary	Application No.		Applicant(s)	
	10/018,451		GRABITZ, ERNST BERNHARD	
	Examiner		Art Unit	
	Dr. Kailash C. Srivastava		1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) Dr. Kailash C. Srivastava. (3)_____

(2) Mr. Spath, Applicants' Representative. (4)_____

Date of Interview: 14 September 2007.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: NONE.

Claim(s) discussed: Those of Record.

Identification of prior art discussed: That of Record.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants' representative authorized the Examiner to amend Claims 56 and 69 according to Examiner's proposed amendment (See attached) to bring this application in a better condition for allowance.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

From: SPATH, T. [tespath@lawabel.com]

Sent: Friday, September 14, 2007 4:46 PM

To: Srivastava, Kailash

Subject: RE: Proposed Amendment for Discussion Purposes; Grabitz; Serial No. 10/018,451; AFS: 205,360

On behalf of the applicant, we thank the Examiner for his further consideration of the issues relating to the use of "hyperic acid" in this application.

Under the circumstances, we confirm applicant's consent to deleting the term from the claims, and authorize the entry of an Examiner's Amendment for this purpose. We understand that this action, along with the correction of minor typographical errors, will put the application in condition for allowance.

Prompt action as indicated is respectfully requested.

Respectfully submitted,

Thomas E. Spath
ABELMAN, FRAYNE & SCHWAB
Attorneys for Applicant
//Thomas E. Spath//

PATENT DOCKET 205,360

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: GRABITZ EXAMINER: SRIVASTAVA
SERIAL NO.: 10/018,451 ART UNIT: 1655
FILED: March 7, 2002
TITLE: INACTIVATED MICROORGANISMS
COMPRISING SUBSTANCES HAVING
PHARMACOLOGICAL ACTIVITY

September 13, 2007

Transmittal via facsimile 571-273-0923
on September 13, 2007

SUBSTITUTE AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

In response to the Office Action of February 7, 2007, please amend the
application as follows:

IN THE CLAIMS:

1-49. (Cancelled)

50. (Currently amended) A process for the preparation of a ~~microorganism's~~ Saccharomyces' cell wall ~~containing wherein said cell wall contains~~ one or more pharmacological or nutritional substances soluble in an aqueous solution, comprising the following steps:

- i) drawing out the endocellular mass of a ~~microorganism~~ Saccharomyces by means of a hypertonic treatment;
- ii) separating the endocellular mass and recovering the ~~microorganism~~ Saccharomyces cell wall; and
- iii) loading one or more pharmacological or nutritional substances soluble in an aqueous solution into the ~~microorganism~~ Saccharomyces cell wall recovered in step ii) by incubating said ~~microorganism's~~ Saccharomyces' cell wall in a hypotonic aqueous solution or an iso-tonic aqueous solution, comprising the pharmacological or nutritional substances.

51. (Currently amended) The process according to claim 50, comprising a further step of chemical or physical inactivation of the ~~microorganism's~~ Saccharomyces' cell wall obtained in step ii) ~~leaving the external membrane of the microorganism~~ unaltered.

52. (Currently amended) The process according to claim 50, wherein the ~~microorganism~~ Saccharomyces' in step i) is Saccharomyces cerevisiae ~~cerevisiae~~

53. (Previously presented) The process according to claim 50, wherein said pharmacological substance is selected from the group consisting of antibiotics, anti-inflammatories, antibacterials, antivirals, antifungals, antiparasitic agents and vaccines.

54. (Previously presented) The process according to claim 53, wherein said antibiotic is oxytetracycline.

55. (Previously presented) The process according to claim 53, wherein said antibacterial is sulphadimethoxin.

56. (Previously presented) The process according to claim 50, wherein said nutritional substance is selected from the group consisting of sodium quercetin, catechin,

isocatechin, aliphatic polyalcohols, polyphenols, flavans, cyanins, resveratrol and hyperic acid.

57. (Previously presented) The process according to claim 50, wherein said nutritional substance is selected from the group consisting of cyanocobalamin, folic acid, thiamine, α -tocopherol and ascorbic acid.

58. (Currently amended) The process according to claim 50, wherein:
in step i) the endocellular mass is drawn out by incubating the ~~microorganism~~ *Saccharomyces* in a hypertonic solution of the same pharmacologically active substance that is to be loaded into the microorganism's *Saccharomyces* cell wall; and

in step iii) said pharmacologically active substance is already present in the solution and is loaded into the ~~microorganism's~~ *Saccharomyces* cell wall with a change of the osmolarity due to dilution of the solution to hypo-tonicity or iso-tonicity.

59. (Currently amended) The process according to claim 50, further comprising a treatment of the ~~microorganism's~~ *Saccharomyces* cell wall with a fixative or a disinfecting agent.

60. (Previously presented) The process according to claim 50, wherein the hypertonic treatment in step i) is obtained by incubation of the microbial cell with or in a hypertonic solution comprising NaCl in concentrations greater than 0.2 M.

61. (Previously presented) The process according to claim 50, wherein said hypotonic treatment in step iii) is obtained by means of a hypotonic solution comprising NaCl in concentrations lower than 0.12M.

62. (Currently presented) The process according to claim 50, wherein the isotonic treatment in step iii) is performed by a 0.9% NaCl isotonic solution, optionally comprising 0.025M sodium citrate ~~0.025M~~.

63. (Currently amended) The process according to claim 62, wherein the 0.9% isotonic solution comprises 0.025M sodium citrate ~~0.025M~~.

64. (Currently amended) The process according to claim 50, wherein[,] said hypertonic treatment in step i) is performed with a solution consisting of 1.0 M NaCl and 0.05 M sodium citrate; said hypotonic treatment in step iii) is performed with a solution consisting of 0.05 M NaCl and 0.005 M sodium citrate.

65. (Previously presented) The process according to claim 50 wherein, said hypertonic treatment in step i) is performed with a solution consisting of 1.0 M NaCl and 0.05 M sodium citrate; said isotonic treatment in step ii) is performed with a solution consisting of 0.9% NaCl and 0.025 M sodium citrate.
66. (Currently amended) A ~~microorganism's~~ Saccharomyces' cell wall loaded with a pharmacological substance selected from the group consisting of antibiotics, anti-inflammatories, anti-bacterials, anti-virals, anti-fungals, anti-parasitic agents and vaccines obtained according to the process of claim 53.
67. (Currently amended) A ~~microorganism's~~ Saccharomyces' cell wall loaded with oxytetracycline obtained according to the process of claim 54.
68. (Currently amended) A ~~microorganism's~~ Saccharomyces' cell wall loaded with sulphadimethoxin obtained according to the process of claim 55.
69. (Currently amended) A ~~microorganism's~~ Saccharomyces' cell wall loaded with a nutritional substance selected from the group consisting of sodium quercetin, catechin, isocatechin, aliphatic polyalcohols, polyphenols, flavans, cyanins, resveratrol, and hyperic acid obtained according to the process of claim 56.
70. (Currently amended) A ~~microorganism's~~ Saccharomyces' cell wall loaded with a nutritional substance selected from the group consisting of cyanocobalamin, folic acid, thiamine, α -tocopherol and ascorbic acid obtained according to the process of claim 57.

REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks. But this amendment claims 50-52, 58, 59, 62-64 and 66-70 have been amended. The amendments to these claims are fully supported in the as-filed specification.

The Examiner erroneously checked both "non-final" and "final" on the Office Action Summary. Clearly, this was a non-final action since it follows an RCE.

The claims which are presently pending are 50-70; inclusive.

Claims 50-65 have been objected to because of certain informalities. These objections are respectfully traversed.

In claim 50 the word "containing" at line 2 has been replaced by the phrase - - wherein said cell wall contains- -.

In claim 51, line 3, the following phrase "external cell membrane of the microorganism" has been deleted.

In claim 58, line 3 after the word "substance" applicants have inserted - -that is- -.

In claim 62, line 3 - -0.025 M- - has been inserted before the phrase "sodium citrate".

At claim 63, line 2 the phrase - -0.025 M- - has been inserted before the phrase "sodium citrate".

At claim 64, line 1 ",", has been inserted after the number "50" and deleted after the word "wherein".

Each instance of the occurrence of the word "microorganism" in the claims has been cancelled and the word - - Saccharomyces - - has been inserted.

Accordingly, since the objections to the claims have been overcome, their withdrawal is solicited.

Claims 50-70 stand rejected under 35 USC §112, first paragraph. This rejection is respectfully traversed.

It is respectfully submitted that by the amendment of the claims to recite -- Saccharomyces--in lieu of "microorganism", the §112, first paragraph, rejection has now been overcome, as will be pointed out hereafter.

In fact, *Saccharomyces* represents a genus characterized by a homogeneous cellular morphology as the strains are unicellular, globose and ellipsoid to elongate in shape, with multilateral budding.

They produce ascospores, located in asci; when stained with Gram stain, ascospores are gram-positive while vegetative cells are gram-negative. An article by Marinoni et al., published in 1999 (the year of filing of the present Application), copy enclosed, confirms that different strains within the genus can freely transfer genetic material and are, therefore, closely related to each other. (An IDS is enclosed).

From a nutritional point of view, a typical characteristic of the *Saccharomyces* genus is its inability to utilize nitrate and the ability to ferment various carbohydrates, which is the reason why they are used in the food industry in fermentation processes.

Therefore, it can be strongly argued that *S. cerevisiae* is representative of the *Saccharomyces* genus, besides being the most studied strain within the genus and among yeasts in general.

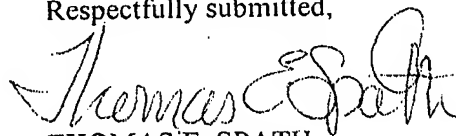
As a consequence, the reference to the genus "*Saccharomyces*" should be considered as being fully supported by the specific examples carried out with the particular strain *S. cerevisiae*.

In view of the above, the §112 rejection has been overcome and should be withdrawn.

The issuance of a Notice of Allowance is respectfully solicited.

Please charge any fees which may be due to our Deposit Account No. 01-0035.

Respectfully submitted,


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